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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,875	06/27/2003	Harish Makker	27542(51308-00090)	7856

33357 7590 11/07/2005

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EXAMINER	
BRUENJES, CHRISTOPHER P	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,875	MAKKER ET AL.	
	Examiner	Art Unit	
	Christopher P. Bruenjes	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-50* is/are pending in the application.

4a) Of the above claim(s) *18-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

WITHDRAWN REJECTIONS

1. The 35 U.S.C. 112 and 103 rejections of claims 1-17 of record in the previous Office Action have been withdrawn due to the cancellation of claims 1-17 in the Paper filed September 29, 2005.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The misnumbered second claim 46 has been renumbered 47.

3. Applicant is advised that should claims 43, 44, and 45 be found allowable, claims 46-50 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to

the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 44, 45, and 47-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 44, 47, and 49, the limitation "said mPEGMA is selected from the group consisting of high molecular weight mPEGMA, medium molecular weight mPEGMA and low molecular weight mPEGMA" renders the claims vague and indefinite. First, it is not understood how the mPEGMA comprising at least three different molecular weights can be chosen only from one molecular weight mPEGMA. Second, it is not understood what is considered "high, medium, or low" molecular weight with regard to mPEGMA. Would mPEGMA with three different molecular weights inherently have molecular weights in which one is higher, one is lower and one is intermediate? Therefore, is the limitation

referring to merely a distribution of molecular weight values or is there a certain range to which high, medium, and low correspond?

Regarding claims 45, 48, and 50, the limitations in these claims render the claims vague and indefinite. It is not understood if the limitation is requiring that the high molecular weight mPEGMA be exactly 1100 and medium exactly 526 and low exactly 360. This contradicts with the claims in which these claims depend, because those claims appear to require three different molecular weights that are chosen from with one molecular weight group. If each molecular weight group is specifically limited to one value, then the limitations of the claims in which these claims depend cannot be met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 32-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al (USPN 5,803,925) in view of Luthra et al (USPN 6,287,707).

Yang et al teaches an intraocular lens inserter cartridge comprising a lubricious coating covalently bound to at least one IOL-contacting surface of said IOL insert cartridge (see abstract). The lubricous coating comprises a reactive substituent component for covalently bonding said lubricious coating to said IOL-contacting surface and a lubricity enhancing component wherein said lubricity enhancing component further comprises a first substituent component for providing lubricity (col.5, l.19-34).

Yang et al fail to teach that the coating also includes a second substituent component effective to reduce hydrolysis of said lubricity enhancing component. However, Luthra et al teach

that polyethylene glycol coatings such as the coating of Yang et al provide medical devices such as the intraocular lens inserter cartridge of Yang et al with a good biocompatible lubricious hydrophilic coating (col.1, l.38-42). However, Luthra also teach that a preferred polyethylene glycol coating for medical devices is a methoxy polyethylene glycol methacrylate (col.2, l.50-52). One of ordinary skill in the art would have recognized that Yang et al and Luthra et al are analogous insofar as both references are concerned with forming biocompatible lubricious hydrophilic coatings on medical devices for insertion in human bodies.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that methoxy polyethylene glycol methacrylate of Luthra et al is a well known polyethylene glycol lubricious coating in the art of medical devices for insertion in human bodies and is substituted for the generic polyethylene glycol lubricious hydrophilic coating of Yang et al, because methoxy polyethylene glycol methacrylates are known in the art to be preferred for the specific problem encountered in Yang et al, as taught by Luthra et al.

Regarding the limitation of claim 32 that the lubricity enhancing component further comprises a second substituent

component effective to reduce hydrolysis of said lubricity enhancing component that is not a hydroxyl group, Yang et al and Luthra et al taken as a whole teach the second substituent as the methoxy portion of the lubricious coating and the fact that the second substituent component reduces hydrolysis is a latent property of the substituent component. Therefore, the references as a whole teach the limitation since the mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention.

Regarding claims 33-35, the lubricity enhancing component is polyethylene glycol (col.7, l.20-24 of Yang et al and col.2, l.50-51 of Luthra et al), which meets the limitations of claims 33-34.

Regarding claims 36-37, the reactive substituent component comprises methacrylate, which is an ethylenically unsaturated group from the class of methacrylic groups.

Regarding claims 38-41, the second substituent component is methoxy, which is a hydrocarbyl group having 1 carbon atom and is also an alcoxy group having 1 carbon atom.

Regarding claims 42-50, Yang et al and Luthra et al taken as a whole teach an intraocular inserter cartridge comprising methoxy polyethylene glycol monomethacrylate covalently bound to at least one IOL-contacting surface of said IOL inserter

cartridge as shown above. The mPEGMA of Luthra et al comprises at least three monomers each having different molecular weights (col.2, l.50-54). One monomer is a methoxy polyethylene glycol methacrylate having a molecular weight of 2000, which is a high molecular weight mPEGMA and at least one other monomer is mPEGMA having a molecular weight of 350, which is a low molecular weight mPEGMA and is approximately 360 (col.4, l.1-15). Note the claims do not require that the mPEGMA contain only mPEGMA monomers and the claims only require that one of the claimed relative molecular weight mPEGMA be present.

ANSWERS TO APPLICANT'S ARGUMENTS

6. Applicant's arguments regarding the 35 U.S.C. 112 and 103 rejections of record have been considered but they are moot since the rejections have been withdrawn.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB CPB
November 3, 2005

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

11/2/05